



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

September 1, 2000

Certified Mail
Return Receipt Requested

David C. Chen M.D.
Diagnostic Medical Group of Southern California
5255 E. Pomona Blvd. #7
Los Angeles, CA 90022

W/L 71-00
Inspection I.D. 1899360006

Dear Dr. Chen:

We are writing to you because on 05/03/2000, your facility was inspected by a representative of the State of CA, acting in behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following level 1 findings at your facility:

Noncompliance Level 1:

Phantom QC records were missing for 10 weeks for unit 3, Lorad Medical Systems Inc., T350, room MOBILE COACH

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility at the close of the inspection.

Letter to Dr. Chen
September 1, 2000
Page 2

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, MQSA Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

Noncompliance Level: 2

- 1. The phantom QC is not adequate for unit 3, Lorad Medical Systems Inc., T350, Room MOBILE COACH because:**
 - The image was not taken at clinical setting.
 - The operating level for vackground density was < 1.20 .
- 2. The time period between the previous and current surveys for x-ray unit 3, Lorad Medical Systems Inc., T350 exceeds 14 months.**
- 3. Not all positive mammograms were entered in the tracking system for site Diagnostic Medical Group of Southern California**

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).*

*This note is not applicable for letters which also address patient notification.

Letter to Dr. Chen
September 1, 2000
Page 3

Please submit your response to:

Director, Compliance Branch
Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, CA 92612-2445

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov>.

If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Beverly Thomas at (949) 798-7708 or Minh Phan at (949) 798-7711.

Sincerely,

A handwritten signature in cursive script, appearing to read "Elizabeth A. Keirle".

Acting District Director